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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/464,303	12/15/99	STAHL G	B0801/7156

HM12/0731

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EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/464,303	Stahl et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on th cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 23, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-41 is/are pending in the applica

4a) Of the above, claim(s) 1-17 and 36-41 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 18-35 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 5, 7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicant's election WITH traverse of Group IV (Claims 18-35) in Paper No. 8, faxed 4-23-01, is acknowledged. Applicant's traversal is on the grounds that it would not be a serious burden to the examiner to examine all the species of Group IV together. However, the examiner disagrees because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, and would constitute a serious undue burden on the examiner, hence restriction for examination purposes as indicated is proper. The restriction is still deemed proper and is therefore made FINAL.

2. Claims 1-17 and 36-41 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

3. Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the attached PTO-948 form.

4. With regard to the IDS filed 4-12-2001, it is noted that reference B4 is a substantial duplicate of Reference B3, and therefore Reference B4 on the 1449 form has been scratched out by the examiner. Further it is noted that Reference B1 is being considered only to the extent of the English language Abstract, absent a translation of the rest of said reference.

5. Priority to the instant filing date of 12/15/1999 has been accorded to claims 19-21, 23-25 and 28-32, and not to the filing date of the claimed priority document (60/112,390, filed 12/15/1998) since the instant claims recite hybridoma cell lines and antibodies which were not disclosed in said priority document. ✓

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 19-21, 23-25 and 28-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 19-21, 23-25 and 28-32 encompass an antibody produced by three hybridomas, which according to papers filed by the applicant, were deposited with ATCC on October

2, 1998, under terms of the Budapest Treaty. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent**, would satisfy the deposit requirements. *See 37 C.F.R. 1.808.*

In addition, the identifying information set forth in *37 C.F.R. 1.809 (d)* should be added to the specification. *See 37 C.F.R. 1.803-1.809* for additional explanation of these requirements, Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required (ATCC, 10801 University Boulevard, Manassas, VA 20110-2209).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claims 33-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33-34 are indefinite in the recitation of "an effective amount" because it is not clear what material is encompassed by the "effective amount". One way to overcome this rejection would be to move the phrase "of the isolated MBL binding peptide" from lines 2-3 of claim 33 and insert said phrase immediately after the phrase of "an effective amount" in line 2 of claim 33.

10. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 18, 22, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Theil et al. (Nature 386:06-510, (April 1997))(IDS).

12. Theil et al teaches a monoclonal antibody to human MBL and pharmaceutical composition thereof, (see entire article, especially page 503, Figure 3). Although said article does not teach that said pharmaceutical composition is effective for treating an

MBL associated disorder, it would inherently do so. Intended use does not carry patentable weight. Therefore, the referenced teachings anticipate the claimed invention.

13. Claims 18, 22, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Endo et al. (Nephrology Dialysis Transplantation (1998) 3:1984-1990) (IDS).

Endo et al. teaches a monoclonal antibody to human MBL and pharmaceutical composition thereof, (see entire article, especially page 1985, column 1, last 5 lines and Figure 1A) and teaches that a deficiency or low level of MBL is associated with an increased risk of infection, and also teaches that glomerular deposition of MBL/MASPs initiated complement activation by the complement pathway in some cases of IgA-Nephropathy, and serves as a trigger for the amplification cycle via the alternative pathway and that said initiation is associated with repeated antigen exposure such as infection (see entire article, especially last full paragraph of article). Although said article does not teach that said pharmaceutical composition is effective for treating an MBL associated disorder, it would inherently do so. Intended use does not carry patentable weight. Therefore, the referenced teachings anticipate the claimed invention.

14. Claims 18, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Super et al. (Clin. Exp. Immunol. (1990) 79:144-150) (IDS).

Super et al teach a monoclonal antibody to human MBL and pharmaceutical composition thereof, (see entire article, especially page 145, column 2, third and fourth full paragraphs). Although said article does not teach that said pharmaceutical composition is effective for treating an MBL associated disorder, it would inherently do so. Intended use does not carry patentable weight. Therefore, the referenced teachings anticipate the claimed invention.

15. Claims 18, 22, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Esekowitz, U.S. Patent 5, 270,199 (1993).

'199 teaches a peptide which is a therapeutically effective fragment of human mannose-binding protein or a human mannose binding protein; the invention features a purified antibody useful for detecting a human mannose binding protein. The antibody is preferably provided as a homogeneous preparation of a monoclonal or polyclonal antibody. The antibody is useful for purification of human mannose-binding proteins or peptides thereof, or for therapeutic treatment of patients. Although said article does not teach that said pharmaceutical composition is effective for treating an MBL associated disorder, it would inherently do so. Intended use does not carry patentable weight. Therefore, the referenced teachings anticipate the claimed

invention.

16. The following is a quotation of *35 U.S.C. § 103* which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

17 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 18 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esekowitz, (U.S. Patent 5, 270,199 (1993) or Theil et al. (Nature 386:06-510, (April 1997))(IDS), or Endo et al. (Nephrology Dialysis Transplantation (1998) 3:1984-1990), or Super et al. (Clin. Exp. Immunol. (1990) 79:144-150) (IDS) in view of Janeway et al (Immunobiology, page 13.8 (1997)) and the Pierce Catalog page T19 and T20 (1995).

Theil et al., Endo et al., Super et al. and the '199 patent teaches as above.

Janeway et al teach that humanization of an antibody produces a monoclonal antibody that are far less immunogenic in humans than the parent mouse antibodies, and thus they can be used for treatment of humans with far less risk of anaphylaxis (see page 13.8).

The Pierce Catalog (1995) teaches F(ab')2 fragment, Fv fragment which encompass the recited Fd fragment as disclosed in the instant specification, and an Fab fragment, and teaches that said fragments possess improved biodistribution properties and lower immunogenicity than intact antibodies (see pages T19-T20, especially column 1 of page T20).

Therefore, it would have ben obvious to one of ordinary skill in the art who wanted to use a composition comprising an MBL inhibitor for therapeutic treatment of human patients, to have used the monoclonal antibody directed to MBL as taught by Esekowitz or Theil et al. or Endo et al. or Super et al. and to have altered said antibody by humanization or fragmentation resulting in an F(ab')2 fragment, Fd fragment, or an Fab fragment as taught by Janeway and the Pierce Catalog, because Janeway and the Pierce Catalog teach that said alterations decrease the antibody's immunogenicity to humans.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
July 30, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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